

REMARKS/ARGUMENTS

Claims 1-10 remain in this application. The following issues are outstanding in the Office Action dated July 6, 2004:

1. Claim 4 was objected to because of an informality;
2. Claims 1 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,458,109 to Henley (hereinafter referred to as “Henley”) in view of U.S. Patent No. 6,120,462 to Hibner et al. (hereinafter referred to as “Hibner”);
3. Claims 2-3, 6 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of Hibner et al. and in further view of U.S. Patent No. 5,611,846 to Overton, et al. (hereinafter referred to as “Overton”);
4. Claims 4, 6 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of Hibner and in further view of U.S. Patent 6, 017,440 to Lewis et al. (hereinafter referred to as “Lewis”);
5. Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of Hibner and in view of U.S. patent No. 5,855,570 to Scherson et al. (“Scherson”) and in further view of Lewis;
6. Claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of Hibner in view of U.S. Patent No. 6,398,767 to Fleischmann (hereinafter referred to as “Fleischmann”) and in further view of Lewis; and
7. Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of Hibner in view of U.S. Patent No. 4,955,391 to Parker et al. (hereinafter referred to as “Parker”) and in further view of Lewis.

Applicant respectfully traverses the rejections, and in light of the following remarks requests reconsideration and withdrawal thereof.

1. Claim Objection

Claim 4 has been amended to correct the typographical error identified by the Examiner. Accordingly, Applicant requests withdrawal of the objection.

2. Claim Rejections – 35 USC §103(a): Henley in view of Hibner

The Examiner has rejected Claims 1 and 5 under 35 U.S.C. §103(a) as being unpatentable over Henley in view of Hibner. Henley was cited for teaching a wound treatment apparatus with a bandage assembly that includes a drainage bandage 20 (screen means) that contacts the wound and a delivery bandage 18 that seals the drainage bandage 20 and the wound site (col. 5, ll. 11-17)), a vacuum source fluidically communicating with the drainage bandage 20 via flexible tube 24, a sensing device (172 or 174) interposed between the delivery bandage and the vacuum source, and a collection canister (164 or 166). Henley was identified as not expressly teaching that the sensing device is placed between the screen means and the vacuum source, nor teaching that the collection canister is placed between the screen means and the sensing device.

The Examiner stated pressure sensors are commonly known in the art, and cited Hibner for teaching a fluid collection system with a main vacuum line 328 [*sic*] that attaches canister 318 to a vacuum pump 330 with a pressure sensor 328 interposed between the canister 318 and the vacuum pump 330 (fig. 14 and col. 15, ll. 51-63). The Examiner concluded it would have been obvious to one of skill in the art to provide the invention of Henley with the connections of Hibner for more accurate pressure sensing. Applicant respectfully notes that element 328

identified by the Examiner as a main vacuum line is a pressure sensor in Hibner. Col. 15, ll. 23-

27. Element 320 is the main vacuum line believed to be referenced by the Examiner.

The Examiner further stated that Applicant failed to state why the placement of the canister is important, and consequently it would have been obvious to place the sensing device between the screen means and the vacuum, and to place the canister between the screen means and the sensing device, since it has been held that rearranging of parts of an invention involves only routine skill in the art.

This rejection is respectfully traversed. Applicant first directs the Examiner to paragraph [0016] of the specification, which states “The detection means is preferably positioned between the canister utilized to collect wound fluids in the traditional V.A.C.® and the vacuum source.” The specification further identifies the importance of any filtration of the wound fluid occurring *after* passage of the fluid through the detection means. *Id.* (emphasis added). Paragraph [0026] further emphasizes the importance of sensor placement to ensure the *greatest accuracy*. Inherently, canister and sensor placement must be carefully made in order to ensure the overall sensing quality remains high.

Accordingly, Applicant has set forth the reasons why the canister placement as set forth in the specification is important, and why arrangement is inherently non-obvious. Careless placement of the canister would result in a non-functional application. Worse, failure to specify canister placement would require one of skill in the art to unduly experiment in order to determine the best mode for practicing the present invention.

Hibner is directed to a control method for an automated surgical biopsy device. The fluid collection system disclosed therein *specifically teaches filtration prior to collection*. Col. 10, ll. 26-29 (“A strainer 134 is attached to the distal end of tissue remover 132 to prevent the passage

of fragmented tissue portions through it and into fluid collection system 22.”). This is a clear teaching away from the invention as claimed in claim 1. Support for the amendment to claim 1 can be found at least in paragraph [0016]. No new matter has been added. Combining Hibner with Henley would place the sensor *after* a filter, which would render results from the sensor reading questionable, if even useful at all. Sensor placement in the present case would not require mere routine skill in the art, inasmuch as incorrect sensor placement, such as that disclosed in Hibner, would fail to achieve the goals of the present invention of identification of infection.

Given these reasons, and the lack of motivation in either Hibner or Henley to combine the two inventions to achieve the invention of claim 1 and dependent claim 5, neither Hibner nor Henley teach the invention as claimed in amended claim 1 and dependent claim 5. Accordingly, withdrawal of the rejection is respectfully requested.

3. Claim Rejections – 35 USC §103(a): Henley in view of Hibner and Overton

The Examiner has rejected Claims 2-3, 6 and 10 under 35 U.S.C. §103(a) as being unpatentable over Henley in view of Hibner and in further view of Overton. The Examiner applied Henley in the same manner as above, except Henley does not teach that the sensing device comprises a gas chromatograph comprising a photo diode. The Examiner stated that Overton teaches a portable gas chromatograph comprising a photoionization (which contains a photo diode) detector, and concluded it was obvious to one of ordinary skill in the art at the time the invention was made to substitute the sensor of Henley combined with Hibner for the gas chromatograph of Overton, in order to detect microorganisms in the drainage fluids.

Henley does not teach the interposition of a sensing device between the delivery bandage and vacuum source, as claimed in independent Claim 1 and stated above. Nor does Overton teach, suggest or otherwise motivate such an interposition. Hibner teaches away from the present invention by teaching a filtration *prior to* sensing, likewise identified above. Accordingly, claims 2 and 3, which depend on claim 1, are allowable at least for the same reasons submitted above.

Likewise, claim 6 has been amended to indicate the criticality of the teaching the sensing device sensing unfiltered wound fluid from the wound bed. Support for this amendment is clearly found at least in paragraph [0016]]. No new matter has been added.

Claim 6 is therefore allowable inasmuch as neither Henley, Hibner nor Overton alone or in combination teach, disclose, or otherwise motivate one of skill to combine the inventions therein to reach the invention of amended claim 6. Claim 10 is submitted to be allowable for the same reasons.

Accordingly, Claims 2-3, 6 and 10 are submitted to be allowable over the art made of record. Withdrawal of the rejections is respectfully requested.

4. Claim Rejections – 35 USC §103(a): Henley in view of Hibner and Lewis

The Examiner has rejected Claim 4, 6 and 10 under USC §103(a) as being unpatentable over Henley in view of Hibner and in further view of Lewis. Claim 4 is submitted to be allowable for the same reasons that claim 1 is now allowable.

With respect to claim 6 and 10, neither Henley, Hibner nor Lewis teach or suggest the invention of claim 6 at least for the reasons above with respect to Henley and Hibner. Lewis does not cure the deficiencies.

Accordingly, Claims 4, 6 and 10 are submitted to be allowable over the cited art.

Withdrawal of the rejection is respectfully requested.

5. Claim Rejections - USC §103(a): Henley in view of Hibner, Scherson and Lewis

The Examiner has rejected Claim 7 as being unpatentable over Henley in view of Scherson and in view of Lewis. Claim 7 depends on amended claim 6, which is allowable at least for the reasons identified in Sections 2 and 3, above.

Accordingly, it is respectfully submitted that the invention of Claim 7 is submitted to be allowable over the cited art. Withdrawal of the rejection is respectfully requested.

6. Claim Rejections - USC §103(a): Henley in view of Hibner, Fleischmann and Lewis

The Examiner has rejected Claim now Claim 8 as being unpatentable over Henley in view of Hibner in view of Fleischmann and in further view of Lewis. Claim 8 depends on amended claim 6, which is allowable at least for the reasons identified in Sections 2 and 3, above.

Accordingly, it is respectfully submitted that the invention of Claim 8 is submitted to be allowable over the cited art. Withdrawal of the rejection is respectfully requested.

7. Claim Rejections – USC §103(a): Henley in view of Hibner, Parker and Lewis

The Examiner has rejected Claim 9 as being unpatentable over Henley in view of Hibner, in view of Parker and in further view of Lewis. Claim 9 depends on amended claim 6, which is allowable at least for the reasons identified in Sections 2 and 3, above.

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Accordingly, it is respectfully submitted that the invention of Claim 9 is submitted to be allowable over the cited art. Withdrawal of the rejection is respectfully requested.

SUMMARY

Believing it has addressed all matters raised by the Examiner's July 6, 2004 Office Action, Applicants respectfully request timely action on the merits. No fees are believed to be required for the amendment. Nevertheless, the Commissioner is permitted to deduct or credit any fees that may be required from Kinetic Concepts Inc. Deposit Account No. 500-326.

In view of the above, it is submitted that the claims are now in condition for allowance. Reconsideration and withdrawal of the rejections is hereby respectfully requested. Allowance of Claims 1-10 at an early date is solicited.

If upon consideration of the above, the Examiner should feel that outstanding issues remain in the present application that could be resolved, the Examiner is invited to contact the undersigned at the telephone number indicated to discuss resolution of such issues.

Applicant respectfully requests favorable consideration.

Respectfully submitted,

A handwritten signature in black ink, reading "Robert W. Mason". The signature is written in a cursive style with a horizontal line underneath the name.

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